

the RoB of included studies as high. Both do not describe a methodology to assess applicability. However, in the CR applicability is discussed with respect to study medication and microbiologic methods, but not generally rejected. The IQWiG report regards interventions in 2 of 3 included studies as not applicable to current health care. In conclusion, the CR identifies preventive effects, but recommends interpreting the results cautiously. The IQWiG report, which, unlike the CR, comprises a dichotomised statement on benefit and harms, regards the benefit of an ASB treatment as not proven due to serious concerns regarding applicability.

Conclusion: Despite differences in detail, overall conclusions regarding the effect of treatment do not differ much. Both works see the need of further randomised trials. The main difference is seen in the significance of applicability and derived conclusions. To date there is no well-developed methodology for assessing applicability. However, different domains of applicability (population, setting, interventions, outcomes, follow-up) should be assessed as recommended in current EUnetHTA guidance.

P1.043

Exploring inconsistencies between observational and experimental studies of selenium and diabetes risk

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Background: Observational and experimental epidemiologic studies that have addressed the relation between intake of the trace element selenium and cancer risk have yielded strongly conflicting results, as recently reported by a Cochrane Review. Most observational studies suggest an inverse association, while randomized controlled trials (RCTs) have indicated a null or direct relation. Little is known about the replication of such inconsistencies when dealing with the risk of other chronic disease. **Objectives:** We investigated the results of observational and experimental studies linking selenium exposure to the occurrence of type-2 diabetes. **Methods:** After a literature search, we identified 12 observational studies (eight cross-sectional and four cohort) and five RCTs. Using a random-effects model, we computed the summary relative risk (RR) of type-2 diabetes along with its 95% confidence interval (CI) in subjects with the highest versus the lowest selenium exposure category in observational studies, and in subjects allocated to selenium compared to placebo in the RCTs. **Results:** Summary RRs were 1.98 (95% CI 1.22 to 3.23) and 1.13 (95% CI 0.15 to 8.45) for cross-sectional studies using serum and toenail selenium for exposure assessment, respectively. Cohort studies based on toenail selenium yielded a summary RR of 0.68 (0.72 to 0.98), while the only study assessing dietary selenium intake gave a RR of 2.39 (1.32 to 4.32). For RCTs, summary RR was 1.10 (1.00 to 1.21) among selenium-supplemented versus placebo. The distinctive feature of the two observational studies (one cross-sectional and one prospective) that failed to find an excess diabetes risk associated with higher selenium exposure was that the

subjects were health professionals. Age, gender, study area and other demographic characteristics did not appear to have influenced the results. **Conclusions:** These results suggest that the ability of observational studies to predict results of RCTs when addressing the health effects of selenium may differ on the basis of the outcome studied (diabetes versus cancer) as well as the indicator used for exposure assessment and the type of population under study.

P1.045

Project on a Framework for Rating Evidence in Public Health (PRECEPT): structure of a draft framework

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Aims: The Project on a Framework for Rating Evidence in Public Health (PRECEPT) is a collaboration between European public health agencies and universities, established in 2012, that aims to establish a framework for evaluating and grading evidence in the field of infectious disease epidemiology, prevention and control. PRECEPT is funded by the European Centre for Disease Prevention and Control (ECDC). This presentation describes the structure and workflow of a draft framework.

Methods and Results: The PRECEPT framework is designed to rate scientific evidence related to four domains that are of high priority in infectious disease prevention and control: disease incidence/prevalence, risk factors for disease, diagnostics and intervention. The framework is grouped into six consecutive working steps, starting from a complex public health question and ending with an evidence statement for each relevant domain. In step 1, approaches are described for identification of relevant questions. In step 2, methodological guidance is provided for the conduct of systematic reviews for these questions. For the appraisal of methodological quality of identified individual studies, 15 different quality appraisal tools are proposed and an algorithm is given to match a given study design with an appropriate tool (step 3). In step 4, a generalized evidence grading scheme based on the GRADE methodology is provided to rate the quality of bodies of evidence for each domain. The evidence appraisal process ends with the preparation of evidence profiles and summary of finding tables (step 5) followed by preparation of an evidence summary for communication of the results (step 6). By applying this methodological framework, the user should be able to evaluate and grade scientific evidence from the four major domains in a transparent and reproducible way. **Outlook:** The draft framework is currently being piloted